Claims

1. A tablet comprising at least two distinct segments, one segment of which comprises as active ingredient predominantly efletirizine and a second segment of which comprises as active ingredient predominantly pseudoephedrine, said segments being composed and formed in such a way that the resulting tablet is substantially free of impurities formed by reaction of efletirizine with pseudoephedrine, and with the proviso that the tablet comprises less than 5 % by weight, relative to the total weight of the pseudoephedrine segment, of an alkalinizing agent.

2. A tablet comprising at least two distinct segments one segment of which comprises as active ingredient predominantly efletirizine and a second segment of which comprises as active ingredient predominantly pseudoephedrine, said segments being composed and formed in such a way that the pharmacokinetic profiles of the efletirizine and pseudoephedrine are substantially the same as in a dosage form containing each as sole active ingredient in the same amount.

3. A tablet according to claim 1 or 2 wherein the pseudoephedrine segment is substantially free of efletirizine.

4. A tablet according to claim 1 or 2 wherein the efletirizine segment is substantially free of pseudoephedrine.

5. A tablet according to any one of the preceding claims wherein the interfacial surface area of the pseudoephedrine segment and efletirizine segment is less than 180 mm^2.

6. A tablet according to any one of the preceding claims wherein the tablet further comprises a barrier segment wherein said barrier segment separates the efletirizine segment and the pseudoephedrine segment.

7. A tablet according to any one of the preceding claims wherein the pseudoephedrine segment comprises less than 5 % by weight, relative to the total weight of the pseudoephedrine segment, of an alkalinizing agent.

8. A tablet according to any one of the preceding claims wherein the tablet comprises a plurality of pseudoephedrine segments.

9. A tablet according to any one of the preceding claims wherein said efletirizine segment is in the form of a compression coating.

10. A tablet according to any one of the preceding claims wherein said efletirizine segment is in the form of a spray coating.

11. A tablet according to any one of the preceding claims wherein the pseudoephedrine segment contains inert pharmaceutical excipients in an amount of 0.75 to 4.5 times that of the pseudoephedrine itself by weight.

12. A tablet according to any one of the preceding claims wherein the efletirizine segment contains inert pharmaceutical excipients in an amount of 5 to 30 times that of the efletirizine itself by weight.

13. A tablet according to any one of the preceding claims wherein the ratio of the total amount of inert pharmaceutical excipients present to the total aggregate amount of all active ingredients is between 1.2 and 6 by weight.

14. A tablet according to any one of the preceding claims wherein the weight ratio of pseudoephedrine to efletirizine is between 2 and 40.

15. A tablet according to claim 14 wherein the weight ratio of pseudoephedrine to efletirizine is about 12.

16. A tablet according to any one of the preceding claims wherein the pseudoephedrine segment comprises between about 10 and 265 mg of pseudoephedrine and the efletirizine segment comprises between about 3 and 70 mg of efletirizine.

17. A tablet according to any one of the preceding claims wherein the pseudoephedrine segment is in a slow release form.

18. A tablet according to any one of the preceding claims wherein the efletirizine is in an immediate release form.

19. A tablet according to any one of the preceding claims wherein the tablet weight is between 200 to 800 mg.

20. A tablet according to any one of the preceding claims wherein the tablet comprises an amount of efletirizine which when dosed to a human subject gives a efletirizine area under the plasma efletirizine concentration versus time curve which is between 80 % and 125 % of the area under the plasma efletirizine concentration versus time curve observed when a dihydrochloride efletirizine immediate release tablet comprising said amount of efletirizine is dosed to same human subject at the same efletirizine dose.

21. A tablet according to any one of the preceding claims wherein the tablet comprises an amount of pseudoephedrine which when dosed to a human subject gives a pseudoephedrine area under the pseudoephedrine plasma concentration versus time curve which is between 80 % and 125 % of the area under the plasma pseudoephedrine concentration versus time curve observed when a pseudoephedrine sustained release tablet comprising said amount of pseudoephedrine is dosed to same human subject.

22. A tablet according to any one of the preceding claims wherein the particle size of the pseudoephedrine present is chosen such that it has a flow index less than 25.

23. A tablet according to any one of the preceding claims wherein the particle size of the pseudoephedrine present is chosen such that it has an ability to settle of less than 30 ml.

24. A tablet according to any one of the preceding claims wherein not more than 10% of the pseudoephedrine present therein has a particle size of less than 100 μm.

25. A tablet according to claim 23 or 24 wherein the particle size of the pseudoephedrine is such that at least 95% of the particles are less than 500 μm and not more than 15% are less than 106 μm.

26. A tablet according to any one of claims 23 to 25 wherein the pseudoephedrine is crystalline.

27. A tablet according to any one of the preceding claims wherein the pseudoephedrine containing segment also contains a methyl cellulose ether derivative having a viscosity of about 11,000 to 21,000 mPa.

28. A tablet according to claim 27 wherein the methyl cellulose ether derivative is a substituted hydroxylated methyl cellulose.

29. A tablet according to claim 27 wherein the methyl cellulose ether derivative is an hydroxypropylmethylcellulose.

30. A tablet according to claim 29 wherein the derivative is an hydroxypropylmethylcellulose (methoxyl : 19 – 24 %, hydroxypropyl : 7 – 12 %), chlorides : max 0.5 %; having an apparent viscosity of 11250 to 21000 mPa and a particle size : min 90 % < 100 mesh.

31. A tablet according to any one of claims 27 to 30 wherein the ratio of hydroxypropylmethylcellulose (HPMC) to the pseudoephedrine is between 0.5 to 2 by weight.

32. A tablet according to any one of the preceding claims wherein the efletirizine containing segment also contains a disintegrant.

33. A tablet according to claim 32 wherein the efletirizine containing segment also contains a disintegrant in the range less than 5 % by weight of efletirizine segment.

34. A tablet according to claim 32 wherein the disintegrant is a cross-linked carboxy methyl cellulose.

35. A tablet according to any one of the preceding claims wherein the efletirizine segment contains excipients including a polyhydroxyl compound having a molecular weight of less than 400.

36. A tablet according to claim 35 wherein the polyhydroxyl compound is a sugar.

37. A tablet according to claim 36 wherein the sugar is lactose.

38. A tablet according to any one of the preceding claims wherein the tablet is a bi-layer tablet, the efletirizine segment being a layer and the pseudoephedrine segment being a layer.

39. A tablet according to claim 38 wherein the weight ratio of the pseudoephedrine layer to the efletirizine layer is between 0.25 to 10.

40. A tablet according to claims 38 or 39 wherein the outer face of each of the two layers has a different shape.

41. A tablet according to claim 40 wherein the tablet has a first face which is the pseudoephedrine layer, having multiple radii of curvature .

42. A tablet according to claim 40 wherein the tablet has a second face which is the efletirizine layer, having a single radius of curvature.

43. A tablet according to anyone of the preceding claims which comprises an additional coating layer.

44. A tablet according to claim 43 wherein the coating layer can act as a taste masking agent.

45. A tablet according to anyone of the preceding claims wherein the tablet is packaged in a moisture protective packaging material.

46. A tablet according to anyone of the preceding claims wherein the tablet is packaged in an oxygen protective packaging material.

47. A tablet according to anyone of the preceding claims wherein the efletirizine segment comprises efletirizine dihydrochloride.

48. Use of a tablet according to anyone of the preceding claims, for the manufacture of a medicament for preventing or treating disorders or conditions associated with rhinitis, cold, flu, cold-like and flu-like symptoms, and allergic rhinitis, relief of nasal congestion, seasonal rhinitis, sneezing, rhinorrhea, nasal and ocular pruritus, redness of the eyes, tearing, sneezing.